



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 30, 2020

Coleen K. Gerber
Scientist
Keller and Heckman LLP
1001 G St. NW, Suite 500 W
Washington, DC 20001

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: VigorOx CR
EPA Registration Number: 65402-13
Application Date: August 4, 2020
Decision Number: 565363

Dear Ms. Gerber:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Avian Reovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

{Front Panel}

VigorOx® CR

Sporicide, Virucide*, Disinfectant

For Use in Clean Rooms and Controlled Areas

Hard Surface [Sterilant] [Sporicide] [Disinfectant] [Virucide*] [Sanitizer]

[Aseptically Filtered at 0.2 µm] [Sterile]

Formulated with Water For Injection Quality Water

Active Ingredients:

Peroxyacetic Acid [CAS# 79-21-0]5.13%

Hydrogen Peroxide [CAS# 7722-84-1].....21.70%

Inert Ingredients:..... 73.17%

Total**100.00%**

**KEEP OUT OF REACH OF CHILDREN
DANGER**



{Note: *Optional GHS Symbol* }

{Note to reviewer: *Include for Customers who require visual hazard symbols*}

{Note to reviewer: *The following reference statements available for various packaging scenarios.*}

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [precautionary statements] [directions for use] [additional precautions] [and] additional product information.]

[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

Reorder {xxxxxxxxxxxxx}	{Lot Label Sticker}	{QR Code}
Lot: {xxxxxxx}		
EXP. {dd-MM-YYYY}		
Net Contents: {(XXX fluid ounces /X Gallon(s)) on Container or on Case (XX/CASE, Container size (yyy))}		

Red dot indicates Sterile {will not appear on non-sterile packages} Rev. MM/YY ●{code}
 After opening use within 30 days.

EPA Reg. No.: 65402-13
EPA Est. No.: 65402-NY-001

Manufactured by:
 PeroxyChem, LLC
 2005 Market Street Ste. 3200
 Philadelphia, PA 19103-7014

Made in USA

FIRST AID

If in Eyes:

Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

If Swallowed:

Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Emergency Number: 1-866-928-0789 (toll free USA) or 1-215-207-0061.

For non-emergency and general information on product use, call 1-610-644-8335.

{End of Front Panel}

{Side/Back Panel}

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. May be fatal if absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear goggles, face shield, or safety glasses. Wear coveralls over long-sleeved shirt and long pants, socks, chemical resistant gloves and chemical resistant shoes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL or CHEMICAL HAZARDS: Strong oxidizing agent. Mix only with water. At temperatures exceeding 156°F, decomposition of VigorOx® CR could occur, releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, mammals, fish and aquatic life. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

DIRECTIONS FOR USE **Read the label before using.**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of

the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

LOCATIONS OF USE: Disinfects clean rooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard, non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

[Sterilization] [/] [and] [Sporicidal]

This product is an effective [sterilant] [and] [sporicide] against *Bacillus subtilis* (ATCC 19659), and *Clostridium sporogenes* (ATCC 3584) on both porous and non-porous hard surfaces. It is effective in the presence of 400 ppm hard water (measured as calcium carbonate equivalent) on visibly clean surfaces with a six hour contact time.

Manufacturing, Filling and Packaging Equipment in Aseptic Processes (non-food contact surfaces)

Prior to use of this product, remove gross soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a [sterilization] [sporicidal] solution by adding 8.5 fluid ounces of this product to 1 gallon of water, or the equivalent 1:15 dilution [(equivalent to 3400 peroxyacetic acid and 14467 ppm hydrogen peroxide)] in potable water. Circulate, coarse spray, or flood the [sterilizing] [sporicide] solution through the system. All surfaces must remain wet for 6 hours. Product contact surfaces must be rinsed with sterile water.

Sporicidal *Clostridium difficile*

This product kills and/or inactivates spores of *Clostridium difficile* on hard, non-porous surfaces that are visibly clean by adding 8.5 fluid ounces of this product to 1 gallon of water, or the equivalent 1:15 dilution [(equivalent to 3400 peroxyacetic acid and 14467 hydrogen peroxide)] in the presence of organic soil.

Special Instructions for Cleaning Prior to Disinfection Against *Clostridium difficile* Spores

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Contact Time: Leave surface wet for 5 minutes with a 1:15 dilution.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. The cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and or scrubbing, until all visible soil is

removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection

This product is an effective disinfectant against vegetative forms of Gram positive and Gram negative bacteria and viruses* on hard, non-porous surfaces. This product is effective against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, Influenza A virus* (H1N1, H3N2, and H5N1 strains), Influenza B virus* and Parainfluenza Virus* Type 3. This product may also be used to disinfect surfaces contaminated with Newcastle Disease virus*, Avian Reovirus*, Avian Infectious Bronchitis Virus*, Infectious Bursal Disease Virus*, and Infectious Bovine Rhinotracheitis Virus*.

Prior to use of this product, remove gross soil particles from surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a disinfecting solution by adding 3.2 fluid ounces of this product to 5 gallons of water or the equivalent 1:200 dilution [(equivalent to 280 ppm peroxyacetic acid and 1195 ppm hydrogen peroxide)] using potable water. Apply this product by wiping, mopping or as a coarse spray. All surfaces must remain wet for 10 minutes. Product contact surfaces must be rinsed with sterile water.

General Environmental Surfaces Sanitization (Non-Food Contact)

This product is an effective inanimate hard, non-food contact surface sanitizer against *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Saccharomyces cerevisiae*.

Sanitization of surfaces such as floors, walls, tables, chairs, benches, drains etc., can be accomplished using the following procedures:

Prior to use of this product, remove gross soil particles from surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a sanitizing solution by adding 1 fluid ounce of this product in 16 gallons of water, or the equivalent 1:2048 dilution [(equivalent to 27 ppm peroxyacetic acid and 117 ppm hydrogen peroxide)] using potable water. Apply this product by wiping, mopping or as a coarse spray. All surfaces must remain wet for 5 minutes. Product contact surfaces must be rinsed with sterile water.

Note: Before using this product on metal surfaces, it is recommended that the diluted solution be tested on a small area to determine compatibility.

In all applications, always prepare a new sporicide/sanitizing/disinfecting solution daily to ensure effectiveness. Do not reuse sanitizing /disinfecting solutions. Dispose of any unused sporicide/sanitizing/disinfecting solution.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Never return this product to the original container after it has been removed.

Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute with large volume of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at room temperatures below 86°F. Do not store on wooden pallets.

DISPOSAL

Pesticide Disposal: VigorOx® CR that is to be discarded should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Dispose of container by permitted onsite incinerator, or by transport to offsite permitted incineration services.

Nonrefillable containers greater than or equal to 5 gallons.

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Empty drums are not returnable to PeroxyChem, LLC unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

Procedure for Leak or Spill

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in spaces. all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

Optional Directions for Use for SIMPLEMIX® Containers

PREPARE [DISINFECTION] [SPORICIDE] USE SOLUTION: Follow SIMPLEMIX® System Container instructions.

SIMPLEMIX® System Container Instructions:

Select SIMPLEMIX® Container

[On 55 Gallon (200 L) Drum label:] {Note to reviewer: to be used with customer supplied pump}

Connect cubic container to the drum

1. Close all valves
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense – Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on the label.

[On 1 Gallon Size Bottle label:]

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [completely] [all the way] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.

[On [16 Fluid Ounce] Trigger Spray Bottle label:]

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [completely] [all the way] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.
7. Follow directions for use on label.

(Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)

{1 Gallon SIMPLEMIX®}



{16 Fluid Ounces SIMPLEMIX®}



{Note: To appear as label end panel for customer use on containers: convenience item.}

User Information
Date Opened/Operator:
<input type="text"/>
Expiration Date:
<input type="text"/>
Area:
<input type="text"/>

Optional Label Claims

- Kills and/or inactivates 99.9999% of spores of *Clostridium difficile* on a hard, non-porous surface.
- Non-Sterile

[Emerging Viral Pathogens Claim – Hard, non-porous surfaces]

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to veterinarians, health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.)

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...following the directions for use for the following organisms on the label:
Enveloped virus	Avian Reovirus

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, non-porous surfaces. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against Avian Reovirus on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against Avian Reovirus on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.